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May 28, 1998

Assistant Commissioner for Patents
Washington, DC 20231
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Re: Patent Application
Our File No. 0383311-0089

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May 28, 1998
Date

Mark Higgins

Transmittal Letter

Dear Sir:

Please find enclosed a patent application as follows:

| | |
|--------------|---|
| Applicant(s) | Mark A. Johanson, et al |
| Title: | BONE ANCHOR AND DEPLOYMENT DEVICE THEREFOR |

- 1) This Transmittal Letter with Express Mail Certificate;
- 2) Specification (15 pp., incl. cover sheet); Claims (9 pp.); Abstract (1 pp.); Drawings (4 sheets);
- 3) Declaration and Power of Attorney (unexecuted);
- 4) A Verified Statement (Declaration) Claiming Small Entity Status 37 CFR 1.9(f) and 1.27(d) Small Business Concern (unexecuted);

- 5) Assignment (unexecuted);
- 6) Return postcard;
- 7) Check in the amount of \$606.00, including:

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| Additional Fees: | |
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| Number of independent claims minus 3, times \$41: $6-3=3$ | 123.00 |
| Multiple Dependent Claims (\$135): | <u>0.00</u> |
| Total Filing Fee | \$ 606.00 |

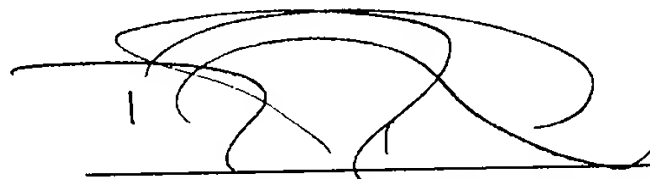
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Kindly acknowledge receipt of the foregoing application by returning the self-addressed postcard.

Respectfully submitted,

5/28/98
Date



David J. Powsner, Reg. No. 31,868

Express Mail No. EI985602710US
Attorney Docket No. 0383311-0089

Applicants: Mark A. Johanson
John Rice
Rickey Hart
James Nicholson

Serial No.:

For: **BONE ANCHOR AND DEPLOYMENT DEVICE THEREFOR**

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9 (F) AND 1.27 (D)) - SMALL BUSINESS CONCERN

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the
concern identified below:

NAME OF CONCERN Innovasive Devices, Inc.

ADDRESS OF CONCERN 734 Forest Street, Marlborough, MA 01752

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled BONE ANCHOR AND DEPLOYMENT DEVICE THEREFOR by the above named applicant described in

- ☒ the specification filed herewith
☐ application serial no.
☐ patent no. , issued

If the rights of the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor(s), who could not qualify as a small

business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____

ADDRESS _____

() Individual () Small Business Concern () Nonprofit Organization

FULL NAME _____

ADDRESS _____

() Individual () Small Business Concern () Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING _____

TITLE OF PERSON _____

ADDRESS OF PERSON 734 Forest Street, Marlborough, Massachusetts

SIGNATURE _____ DATE _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION FOR

BONE ANCHOR AND DEPLOYMENT DEVICE THEREFOR

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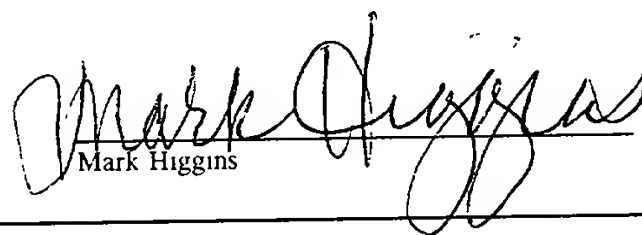
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May 28, 1998
Date


Mark Higgins

REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority of and is a continuation-in-part of U.S. Application Serial No. 08/595,772, filed on February 2, 1996 (Attorney Docket: 0383311-0040) and of Application Serial No. 08/814,149, filed on March 10, 1997 (Attorney Docket: 0383311-0070) and, thereby, of U.S. Application Serial No. 08/163,130 (now U.S. Patent No. 5,725,529) filed on December 6, 1993 (Attorney Docket: 0383311-0019) and, thereby, of U.S. Application Serial No. 08/765,445 (now U.S. Patent No. 5,268,001) filed on September 25, 1991 (Attorney Docket: 0383311-0018) and, thereby, of U.S. Application Serial No. 08/588,025 (now abandoned) filed on September 25, 1990 (Attorney Docket: 0383311-0043).

BACKGROUND OF THE INVENTION

The present invention is directed to a bone anchor for attaching tissue to bone, and to a device for deploying such an anchor in bone. More specifically, the invention is directed to a bone anchor which employs a "floating" washer that conforms to the angle of the bone surface to hold tissue in place, and to a deployment device having a plunger-like configuration that facilitates deployment of such an anchor.

Soft tissue, such as tendon, may become detached from a patient's bone as a result of injury or a medical procedure. In either case, the tissue must be re-attached in order to permit healing. Medical devices used to perform this function are known as bone anchors.

Traditionally, bone anchors were merely tacks or nails that were hammered through a patient's soft tissue and directly into the patient's bone. Anchors of this type, however, had many deficiencies. For example, they were prone to coming out of the bone, particularly in cases where patients were relatively active. In addition, because the

anchors were hammered directly into the bone, deployment was difficult and could sometimes result in hairline fractures.

5 In recent times, more sophisticated bone anchors have been developed which alleviate some of the problems mentioned above. For example, many bone anchors now include prongs or something similar, which reduce the chances that the anchor will dislodge from the bone. Likewise, bone anchors have now been developed which can be inserted into pre-formed holes in bone, rather than being hammered.

10 When affixing tissue directly to bone, it is often desirable to deploy the bone anchor at an angle that is normal to the bone surface. If this is not done, then sufficient contact may not be achieved with the surrounding tissue to hold the tissue in place. Understandably, achieving such placement can be difficult when the anchors are placed endoscopically.

15 In addition to the foregoing, the force required to deploy a conventional bone anchor often makes deployment problematic. Driving a tack or nail-like anchor into bone, for example, is difficult if the surgeon does not have adequate leverage on the bone to counterbalance the force of impact.

20 Thus, there exists a need for a bone anchor which does not need to be deployed at a precise angle in order to attach tissue to bone reliably, and a device for deploying such an anchor which does not require a surgeon to impart substantial counterforce against the device during bone anchor deployment.

25 In view of the foregoing, an object of the invention is to provide improved bone anchors and methods for deployment thereof. A related object is to provide improved devices for deploying such anchors.

A further object is to provide anchors that attach tissue firmly and reliably, regardless of the angle of deployment.

A still further object is to provide anchors, methods and devices for deployment
5 thereof suitable for use in endoscopic procedures.

Yet a still further object is to provide such anchors, methods and devices that can be deployed easily and without application of unnecessary leverage or counterforces.

SUMMARY OF THE INVENTION

The present invention addresses the foregoing objects by providing a rivet-like bone anchor having a floating washer at its head that can adapt to an angled bone surface and, thereby, better secure a tissue thereto. The invention also provides a deployment tool that permits the anchor to be deployed without application of unnecessary counterforce.

Thus, according to one aspect, the present invention is a bone anchor which includes a rivet, an expandable sleeve, and a washer. The rivet includes a head and an elongate body having proximal and distal ends, the head being mounted on the proximal end of the elongate body. The expandable sleeve has an inner bore adapted to receive the rivet body. The washer "floats" at a proximal end of the sleeve. As the rivet is inserted into sleeve, the sleeve expands into an interference fit with the bone. The head of the rivet, moreover, forces the floating washer into contact with the tissue at an angle that conforms to that of the underlying bone surface.

In other aspects of the invention, an external surface of the expandable sleeve and/or the rivet has one or more annular ribs, threads or protrusions. These increase the strength of the interference fits between the rivet and the sleeve, as well as between the sleeve and the bone, thereby reducing the chances that the anchor will dislodge. The washer can likewise include ridges, teeth or other protrusions that enhance fixation of the tissue upon deployment.

In still other aspects of the invention, the bone anchor includes a housing which is frangibly coupled to the expandable sleeve via breakable flanges. The housing, which can be used to affix the anchor to the delivery device, can also protect and store the rivet prior to deployment. During deployment, the head of the rivet breaks the flanges of the housing, thereby freeing the housing from the anchor.

According to another aspect, the present invention provides an apparatus for deploying a bone anchor of the type described above. The apparatus includes an outer tube, the distal end of which can hold the anchor housing, e.g., via a screw fit. A rod, which is slidably disposed within the bore of the tube, can be used to push the rivet into the expandable sleeve so that the sleeve expands into the bone, so that the floating washer is forced into position against the bone surface, and so that anchor is broken away from the housing. This can be effected, for example, by squeezing the proximal ends of the outer tube and the rod together, e.g., in the manner that the end of a syringe is squeezed.

By virtue of this design, the counterforce which a surgeon must impart to the apparatus during bone anchor deployment is eliminated. More specifically, because the outer tube is coupled to the expandable sleeve and because the rod pushes on the rivet, there are no net forces that must be counterbalanced during at least the initial stage of deployment.

According to another aspect, the present invention is a method of deploying a bone anchor of the type described above using a deployment device of the type described above. The method includes pulling the tissue into position over the bone with a guide wire, e.g., a pin or K-wire, and drilling a hole in the bone, e.g., with a drill bit fitted over the end of the guide wire. With the guide wire holding the tissue in place over the bone hole, the bone anchor is then threaded down the wire and into position for deployment (e.g., with the sleeve in the bone hole and the floating washer resting against the tissue and bone surface). The deployment device, which is preferably threaded to the anchor, is simultaneously slid into position for deployment.

According to yet another aspect of the invention, the tissue is pierced and pulled into position over a predrilled bone hole via a guide or probe integral to, and extending from, the distal end of the outer tube. With the guide or probe holding the tissue in place over the bone hole, the bone anchor is passed through the outer tube, threaded through the tissue and into the bone hole.

Still further aspects of the invention provide for securing the sleeve into the bone hole by threading it through clockwise (or counter-clockwise) rotation of the outer tube.

5 The rivet is deployed by squeezing the proximal end of the outer tube and inner rod together in a syringe-like motion, or put another way, by applying downward force to the inner rod and upward force to the outer tube thereby forcing the rivet out of the housing and into the expandable sleeve. Continued application of these forces, at least partially sets the floating washer in conformity to the angle of the underlying bone surface and causes the frangible flanges to break, thereby freeing the housing from the sleeve. Once the anchor is at least partially deployed, the deployment device and attached housing (sans anchor) are removed from the site. The inner tube of the deployment device is then rethreaded down the K-wire so that its distal end re-abuts the head of the rivet. By applying force (e.g., tapping) to the proximal end of the inner rod, the rivet is fully set, fully fixing the washer at the angle of the underlying bone surface.

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A more complete understanding of the invention can be obtained by reference to the following detailed description of the preferred embodiments thereof in connection with the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the invention may be attained by reference to the drawings, in which:

5

Figure 1 is a close-up view of a bone anchor in accordance with the present invention, in which the bone anchor's rivet is not deployed;

10 Figure 2 is a close-up view of a bone anchor in accordance with the present invention, in which the bone anchor's rivet is deployed;

Figure 3 shows a bone anchor deployment device in accordance with the present invention;

15 Figure 4 shows an outer tube of the bone anchor deployment device shown in Figure 3;

Figure 5 shows an inner rod of the bone anchor deployment device shown in Figure 3; and

20

Figures 6 through 12 show a process for deploying the bone anchor shown in Figure 1 into a bone using the bone anchor deployment device shown in Figure 3.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figures 1 and 2 are close-up, cut-away views of a bone anchor according to the present invention. As shown in Figure 1, bone anchor 1 includes housing 2, expandable sleeve 4, rivet 6, floating washer 7, breakable flanges 9, and threading 10. In preferred embodiments of the invention, some or all of these components are made of a bioabsorbable material which dissolves in a patient's body over a period of time leaving little or no trace. Alternatively, bone anchor 1 may be made of other biocompatible materials, such as conventional plastics or the like.

Rivet 6 is comprised of head 11, elongate body 12, tapered tip 14, and a centerbore (not shown) running therethrough. Head 11 is located at the proximal end of rivet 6 and has a diameter which is greater than that of either elongate body 12 or tapered tip 14. Head 11 also includes undersurface 15. Undersurface 15 can be formed with a spherical radius or, alternatively, angled relative to a longitudinal axis of the elongate body. Thus, as shown in the illustration, the undersurface is angled relative to plane 16 which, as shown in Figure 1, bisects elongate body 12 at a right angle. Preferably, undersurface 15 is angled at 45 degrees; although other angles may be used. Elongate body 12 includes annular ribs 8 on an outer surface thereof, which are adapted to aid in maintaining rivet 6 in sleeve 4. It should be noted, however, that elongate body 12 need not include annular ribs in order to perform its function. Tapered tip 14 is located at the distal end of rivet 6, and has a diameter which decreases gradually from the diameter of elongate body 12 to less than that of inner bore 19 of expandable sleeve 4.

Prior to deployment of bone anchor 1, rivet 6 is housed in housing 2, as shown in Figure 1. Housing 2 is preferably cylindrical in shape and includes threading 10 at first open end 20. Threading 10 is adapted to connect bone anchor 1 to a bone anchor delivery device, such as that described in detail below. Housing 2 is integrally coupled with expandable sleeve 4 via flanges 9, which are sized to break in response to either

downward or upward pressure against head 11 so as to disconnect (i.e., free) housing 2 from expandable sleeve 4.

Expandable sleeve 4 includes inner bore 19, as noted above, and is fabricated of a material which is capable of expanding into an interference fit with a bone hole. Inner bore 19 has a diameter that is less than the diameter of elongate body 12, but which is greater than or equal to a diameter of tapered tip 14. As a result of these dimensions, expandable sleeve 4 is able to receive rivet 6, distal-end-first. As described in more detail below, expandable sleeve 4 expands as elongate body 12 moves into expandable sleeve 4, eventually resulting in the arrangement shown in Figure 2, in which expandable sleeve 4 is fully expanded. When bone anchor 1 is deployed in a hole in a bone, this expansion results in an interference fit between expandable sleeve 4 and the bone. To aid in expansion, expandable sleeve 4 also may include radial or longitudinal slots (not shown) which runs all or part-way along expandable sleeve 4. In addition, a membrane may also be included on the slot, which permits expansion while, at the same time, guarding against breakage of expandable sleeve 4.

The outer surface of expandable sleeve 4 includes annular ribs or threads 17 along at least a portion thereof. Annular ribs or threads 17 contact sides of a bone hole into which bone anchor 1 is implanted and, when expandable sleeve 4 is expanded, assist in maintaining bone anchor 1 in the bone. This feature of the invention is described in more detail below.

Disposed around the outer surface of expandable sleeve 4 is washer 7. Washer 7 may be of any shape, i.e., it may be elliptical, circular, etc., and may include ridges or other protrusions on its undersurface for improved contact with tissue or bone. When bone anchor 1 is not deployed in a bone, washer 7 "floats", meaning that it is capable of at least longitudinal motion and limited angular motion relative to expandable sleeve 4. Washer 7 may be capable of lateral motion relative to expandable sleeve 4 as well. Thus, referring to Figure 1, washer 7 is capable of longitudinal motion along line 22 and

of angular motion at, e.g., angles 23 and 24. This longitudinal motion and angular rotation is possible when expandable sleeve 4 is fully unexpanded and, preferably, also when it is fully expanded. Washer 7 also has a top surface 25 which abuts with undersurface 15 of rivet 6, and which may or may not be angled or radiused relative thereto. In the embodiment shown in Figures 1 and 2, top surface 25 of washer 7 is not angled or radiused.

Bone anchor 1 is deployed into a hole in a bone using a plunger-like deployment device, such as that shown in Figure 3. As shown in Figure 3, bone anchor deployment device 26 is comprised of tube 27 and rod 29. These components may be fabricated of any material; although stainless steel is used in the preferred embodiment. Tube 27, which is shown in Figure 4, has a bore (not shown) therethrough for receiving rod 29. At distal end 30, the inner surface of tube 27 includes threading (not shown). This threading is adapted to mate with threading of a bone anchor, such as bone anchor 1, in order to hold the housing of the bone anchor substantially immobile during deployment. Tube 27 also includes "T"-shaped handle 31 at its proximal end. Handle 31 interacts with knob 32 of rod 29 so as to limit the motion of rod 29 relative to tube 27.

In this regard, rod 29, which is shown in Figure 5, is removably disposed within the bore of tube 27 and is slidable therein. That is, rod 29 can be removed from tube 27 merely by sliding rod 29 out of tube 27. In addition, rod 29 is capable of sliding within tube 27 such that distal end 34 of rod 29 extends out from tube 27 (see Figure 3). This feature of rod 29 makes it possible for rod 29 to move within at least a portion of the housing of a bone anchor connected to tube 27, as described in more detail below. As noted above, rod 29 also includes knob 32, which contacts handle 31 of tube 27 in order to limit the motion of distal end 34 relative to tube 27. Finally, rod 29 includes a centerbore (not shown) which is capable of receiving a guide wire, such as a K-wire and/or the like.

Figures 6 through 12 explain operation of both bone anchor 1 and deployment device 26 in the context of deploying a bone anchor into a bone during an endoscopic or other surgical procedure. To initiate such a procedure, a K-wire is inserted through the tissue (e.g., tendon) and into the bone at which a bone anchor is to be deployed. A hole is then formed in the bone at that location, e.g., via a drill bit or other cutting device disposed at the distal end of the K-wire. In this regard, hole 37 can be formed by any conventional means. In preferred embodiments of the invention, however, a drill bit or other cutting device (not shown) is slid over K-wire 36 so as to secure the drill bit to K-wire 36 in order to drill hole 37. Thereafter, the drill is removed from K-wire 36. In these embodiments of the invention, a drill guide which is used with such a drill may take the place of the K-wire entirely. The following, however, assumes that a K-wire is used. The result of these steps is shown in Figure 6, namely K-wire 36 in hole 37.

After, before or during formation of hole 37 in bone 39, a bone anchor, such as that shown in Figure 1, is installed in a bone anchor deployment device, such as that shown in Figure 3. Specifically, with reference to Figure 6, housing 2 of bone anchor 1 is screwed into inner threads of tube 27 on deployment device 26. Once this has been done, bone anchor deployment device 26 and bone anchor 1 are slid over K-wire 36 via respective throughbores of sleeve 4, rivet 6 and rod 29. This is shown in Figure 6.

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Next, as shown in Figure 7, expandable sleeve 4 on bone anchor 1 is inserted through soft tissue 40 and into hole 37 of bone 39. Since expandable sleeve 4 is not expanded at this stage of the deployment process, little actual pressure is required on the part of the surgeon in order to insert expandable sleeve 4 into hole 37. As shown in Figure 7, rod 29 may also be moved into contact with rivet 6 at this point by pressing down on knob 32. This pressure may be applied by any means, such as by a surgeon "squeezing" handle 31 and knob 32 together using one hand in a syringe-like manner. Alternatively, hammer blows may be applied to knob 32 while holding tube 27 in place.

expandable sleeve 4. One advantage of the present invention is that these actions may be performed concurrently. More specifically, as noted above, bone anchor 1 includes flanges 9 which break when sufficient force is applied thereto. In the present invention, this force may comprise either contact with head 11 during downward movement of rivet 6 into expandable sleeve 4, or contact with head 11 during upward movement of tube 27. In this regard, to break flanges 9 during upward movement of tube 27, downward pressure is retained on rod 29 and upward pressure is applied to tube 27.

In any event, as shown in Figure 10, once flanges 9 break, deployment device 26, with housing 2 still attached thereto, can be slid off of K-wire 36, leaving rivet 6, washer 7, and expandable sleeve 4 within bone 39. Final deployment then can begin by disconnecting rod 29 from tube 27 (i.e., by sliding rod 29 out of tube 27) and sliding rod 29 back over K-wire 36, as shown in Figure 11. Washer 7 is then set in place by applying a force to knob 32 of rod 29 by way of hammer blows or the like. Because this additional force can be applied via hammer blows or the like, the need for a surgeon to exert counterforce during final deployment is reduced.

The additional force applied above causes rivet 6 to move substantially all the way into hole 37, thereby resulting in firm contact between head 11 and washer 7. As a result of this contact, head 11 forces washer 7 against tissue 40 so that washer 7 is firmly sandwiched between head 11 and tissue 40. In this regard, since washer 7 floats relative to bone surface, head 11 forces washer 7 against tissue 40 so that washer 7 is substantially parallel to a surface of bone 39, i.e., so that washer 7 is disposed at an angle that substantially conforms to a surface of the underlying bone (see Figure 12) . The angle or radii of the undersurface of head 11 described above facilitates this placement. As a result, washer 7 is able to hold tissue 40 in place. Thus, by using a floating washer in this manner, the invention reduces the need to implant the bone anchor at a precise angle relative to the bone.

The present invention has been described with respect to particular illustrative embodiments. It is to be understood that the invention is not limited to the above-described embodiments and modifications thereto, and that various changes and modifications may be made by those of ordinary skill in the art without departing from
5 the spirit and scope of the appended claims.

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1. A bone anchor comprising:

a rivet which includes a head and an elongate body having proximal and distal ends, the head being mounted on the proximal end of the elongate body;

an expandable sleeve having an inner bore adapted to receive the elongate body of the rivet; and

a washer which floats at an end of the expandable sleeve which first receives the rivet;

wherein, as the rivet is received in the expandable sleeve, the sleeve expands in an interference fit with surrounding bone and the head of the rivet forces the washer into contact with tissue adjacent to the bone, the washer being forced into contact with the tissue at an angle that conforms to an angle of a surface of the bone.

2. A bone anchor according to claim 1, wherein an external surface of the expandable sleeve includes one or more protrusions.

3. A bone anchor according to claim 1, wherein the rivet includes a centerbore which is capable of receiving any of a guide wire, guide pin and K-wire.

4. A bone anchor according to claim 1, further comprising:

a housing which is frangibly coupled to the expandable sleeve via breakable flanges, the housing being adapted to store the rivet prior to insertion of the rivet into the expandable sleeve, and being adapted to affix the bone anchor to a delivery device;

wherein, during deployment of the bone anchor, the head of the rivet breaks the flanges of the housing, thereby freeing the housing from the bone anchor.

5. A bone anchor for attaching tissue to bone, the bone anchor comprising:

a rivet having an elongate body and a head disposed on a proximal end thereof;

an expandable sleeve for insertion into an opening in a bone, the expandable sleeve having an inner bore adapted to receive at least a portion of the elongate body of the rivet; and

a floating washer that is disposed about the expandable sleeve and that floats relative thereto;

wherein motion of the portion of the elongate body of the rivet within the inner bore of the expandable sleeve from a proximal end to a distal end thereof causes (i) the expandable sleeve to expand into an interference fit with the bone, and (ii) secures the floating washer relative to the bone.

6. A bone anchor according to claim 5, wherein the floating washer is secured to the bone at an angle that substantially corresponds to a surface of the bone.

7. An apparatus for deploying a bone anchor into a bone, the bone anchor having a housing which stores a rivet, an expandable sleeve which is frangibly coupled to the housing and into which the rivet is inserted, and a washer which floats relative to the expandable sleeve, the apparatus comprising:

an outer tube having a bore therethrough and proximal and distal ends, the distal end being adapted to hold the housing of the bone anchor; and

a rod, which is slidably disposed within the bore of the tube, and which is adapted to push the rivet from the housing and into the expandable sleeve so as to force the expandable sleeve to expand into bone;

wherein forcing the rivet into the expandable sleeve causes the washer to be forced into position relative to a surface of the bone and causes the housing to break away from the expandable sleeve.

8. An apparatus according to claim 7, wherein the proximal end of the tube includes a tube handle and the distal end of the tube includes threading on an inner surface of the tube, the threading being adapted to hold the housing in place;

wherein the rod has a proximal end and a distal end, the proximal end of the rod having a knob and the distal end of the rod contacting the rivet in the housing; and

wherein the rod knob is adapted to contact the tube handle during deployment of the bone anchor so as to limit motion of the distal end of the rod relative to the tube.

9. An apparatus according to claim 7, wherein the rod includes a centerbore which is capable of receiving any of a guide wire, guide pin and K-wire.

10. A bone anchor for attaching tissue to a bone, the bone anchor comprising:

a rivet which includes a head and an elongate body having proximal and distal ends, the head being mounted on the proximal end of the elongate body;

an expandable sleeve which is adapted to move between an unexpanded state and an expanded state, the expandable sleeve having an inner bore which is adapted to receive the elongate body of the rivet distal-end-first so as to cause the expandable sleeve to go from the unexpanded state to the expanded state; and

a washer which surrounds the expandable sleeve and which is capable of both longitudinal motion and of limited angular rotation relative to the head of the rivet, wherein the head of the rivet is adapted to sandwich the washer between the tissue and the head of the rivet when the bone anchor is deployed in the bone so as to hold the tissue substantially in place relative to the bone.

11. A bone anchor according to claim 10, wherein the elongate body has a first diameter and, when the expandable sleeve is in an unexpanded state, the inner bore of the expandable sleeve has a second diameter which is less than the first diameter; and

wherein the distal end of the elongate body comprises a tapered tip, the tapered tip having a diameter which gradually decreases to less than the second diameter of the inner bore.

12. A bone anchor according to claim 10, wherein an external surface of the expandable sleeve includes one or more protrusions.

13. A bone anchor according to claim 10, wherein the rivet includes a centerbore which is capable of receiving any of a guide wire, guide pin and K-wire.

14. A bone anchor according to claim 10, further comprising a housing which is removably connected to the expandable sleeve via breakable flanges, the housing being adapted to store the rivet prior to insertion of the rivet into the expandable sleeve;

wherein the head of the rivet is adapted to contact the breakable flanges during deployment of the bone anchor so as to break the breakable flanges, thereby disconnecting the housing from the expandable sleeve and leaving the bone anchor in the bone.

15. A bone anchor according to claim 14, wherein the housing has a substantially cylindrical shape and mates to a deployment device used to deploy the bone anchor in bone.

16. A bone anchor according to claim 10, wherein the head of the rivet has an undersurface for contacting the washer, the rivet having an undersurface that is any of radiused or angled relative to an axis of the elongate body.

17. A bone anchor according to claim 10, wherein the washer has a top surface which interacts with the head of the rivet and which is any of radiused or angled relative to an undersurface of the head of the rivet.

18. A bone anchor according to claim 10, wherein, when the bone anchor is deployed in the bone, the rivet holds the washer at an angle relative to the head of the rivet such that the washer is substantially parallel to a surface of the bone.

19. A bone anchor according to claim 10, wherein at least one of the rivet, the washer, and the sleeve are bioabsorbable.

20. A bone anchor according to claim 10, wherein the rivet includes one or more annular ribs.

21. A bone anchor according to claim 10, wherein the sleeve may include one or more slots which runs at least part way along the sleeve.

22. An apparatus for deploying a bone anchor into a bone, the bone anchor having a housing which stores a rivet and a sleeve which receives the rivet from the housing, the apparatus comprising:

a tube having a bore therethrough, the tube being adapted to hold the housing such that the housing is substantially immobile relative to the tube;

a rod which is removably disposed within the bore of the tube, the rod being slidably movable within the tube and within at least a portion of the housing;

wherein the rod is capable of movement between a first location in the tube, a second location in the housing at which the rod forces the rivet out of the housing and into the sleeve, and a third location outside of the tube.

23. An apparatus according to claim 22, wherein the tube includes a proximal end and a distal end, the proximal end of the tube having a tube handle and the distal end of the tube having threading on an inner surface of the tube, the threading being adapted to hold the housing in place;

wherein the rod has a proximal end and a distal end, the proximal end of the rod having a rod knob and the distal end of the rod contacting the rivet in the housing; and

wherein the rod knob is adapted to contact the tube handle during deployment of the bone anchor so as to limit motion of the distal end of the rod relative to the tube.

24. An apparatus according to claim 22, wherein the rod includes a centerbore which is capable of receiving any of a guide wire, a guide pin and a K-wire.

25. A method of deploying a bone anchor into a bone using a bone anchor deployment device, where (i) the bone anchor has a housing which stores a rivet and a sleeve which receives the rivet from the housing, the sleeve being connected to the housing by breakable flanges, (ii) the bone anchor deployment device has a tube which holds the housing in place and a rod within the tube which is movable relative to the tube and within the housing held by the tube, and (iii) the rivet, the sleeve, and the rod each have a throughbore, the method comprising the steps of:

positioning a distal end of a K-wire at a location in bone where the anchor is to be deployed;

drilling a hole in the bone at that location;

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inserting the sleeve into the hole in the bone by sliding the bone anchor and the bone anchor deployment device over the K-wire via respective throughbores of the sleeve, the rivet, and the rod;

deploying the rivet in the sleeve by applying downward pressure to the rod relative to the tube so as to force the rod into the housing held by the tube, thereby forcing the rivet out of the housing; and

removing the housing from the sleeve while leaving the sleeve and the rivet in the hole in the bone, the removing step removing the housing by retaining a force on the rod and applying a counterforce to the tube so as to cause the breakable flanges to break, thereby disconnecting the housing from the sleeve.

26. A method according to claim 25, further comprising the steps of:

removing the deployment device, including the housing of the bone anchor, from the guide wire, guide pin and K-wire

disconnecting the rod from the tube;

sliding the rod back over the K-wire so that the rod is in contact with the head of the rivet; and

applying force to the rod so as to move the rivet still further into the sleeve.

27. A method according to claim 26, wherein the rod includes a knob and the pressure is applied to the rod by hammering the knob of the rod.

28. A method according to claim 26, wherein the bone anchor further comprises a washer which is disposed around the sleeve and which is capable of both longitudinal motion and limited angular rotation relative to the sleeve; and

wherein forcing the rivet still further into the sleeve causes the rivet to set the washer at an angle relative to the head of the rivet such that the washer is substantially parallel to a surface of the bone.

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ABSTRACT

A rivet-like bone anchor has a floating washer at its head that can adapt to an angled bone surface and, thereby, better secure a tissue thereto. The anchor includes a rivet, an expandable sleeve, and a washer. The rivet includes a head and an elongate body having proximal and distal ends, the head being mounted on the proximal end of the elongate body. The expandable sleeve has an inner bore adapted to receive the rivet body. The washer "floats" at a proximal end of the sleeve. As the rivet is inserted into sleeve, the sleeve expands into an interference fit with the bone. The head of the rivet, moreover, forces the floating washer into contact with the tissue at an angle that conforms to that of the underlying bone surface. A deployment tool permits the anchor to be deployed without application of unnecessary counterforce. The tool includes an outer tube, the distal end of which can hold the anchor housing, e.g., via a screw fit. A rod, which is slidably disposed within the bore of the tube, can be used to push the rivet into the expandable sleeve so that the sleeve expands into the bone, so that the floating washer is forced into position against the bone surface, and so that anchor is broken away from the housing. This can be effected, for example, by squeezing the distal ends of the outer tube and the rod together, e.g., in the manner that the end of a syringe is squeezed.

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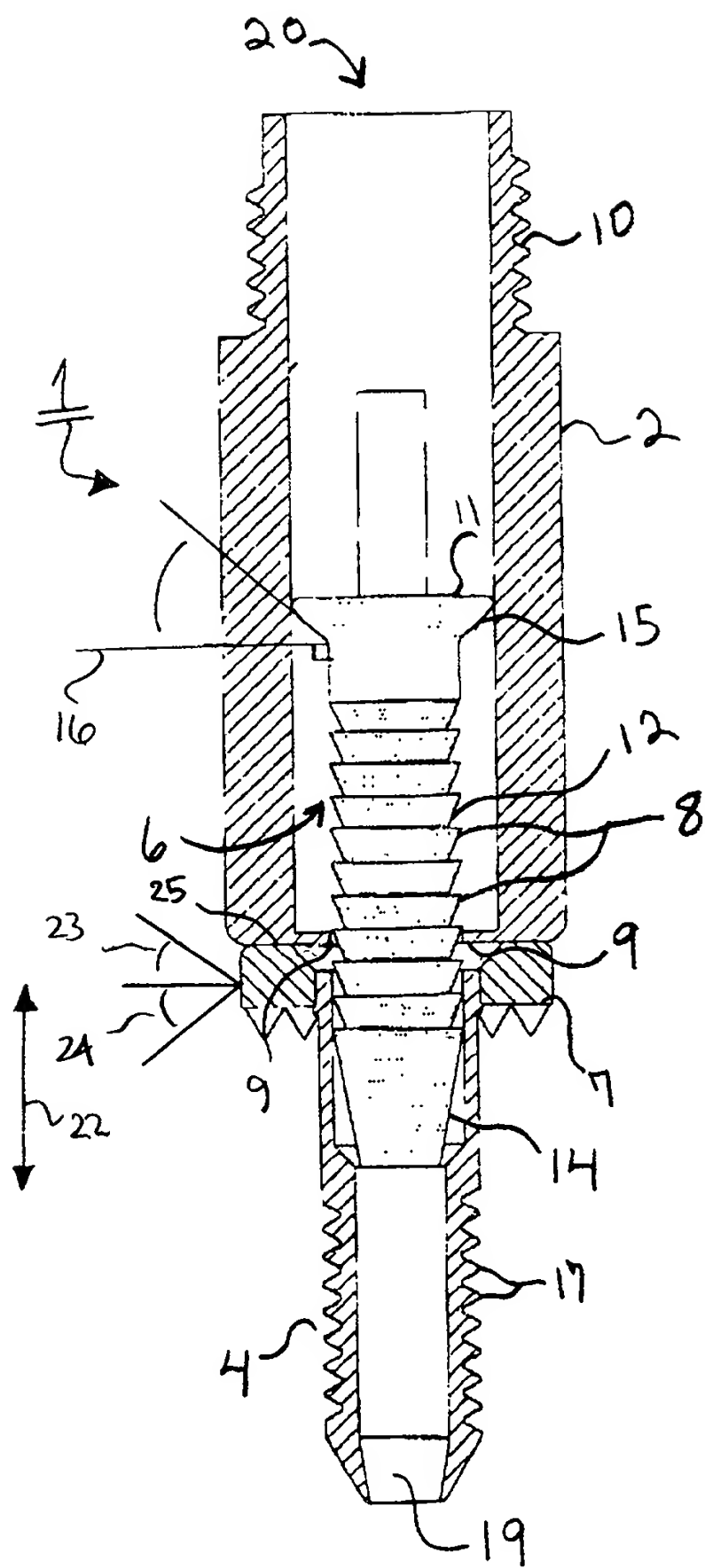


FIG. 1

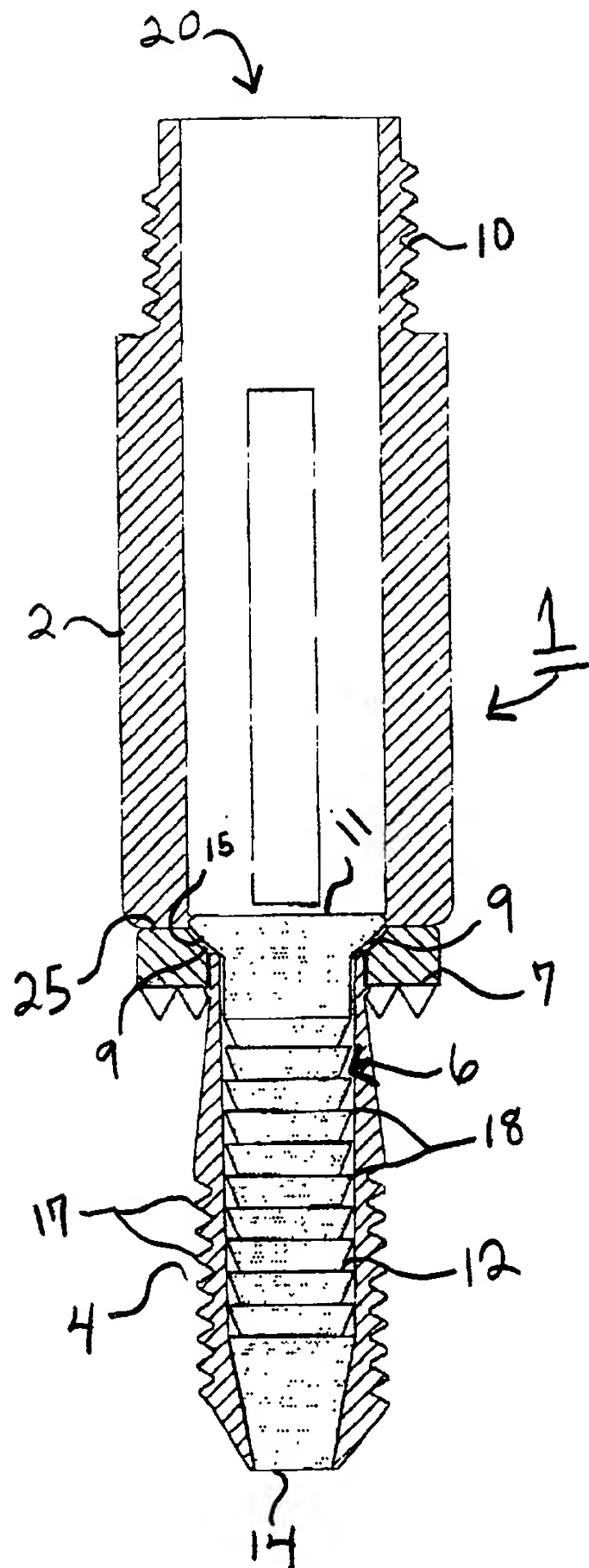
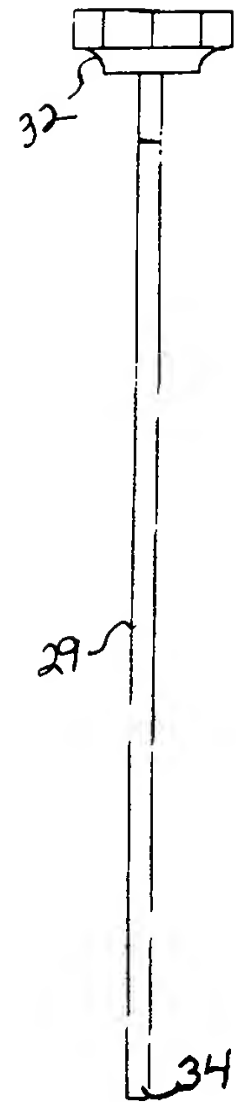
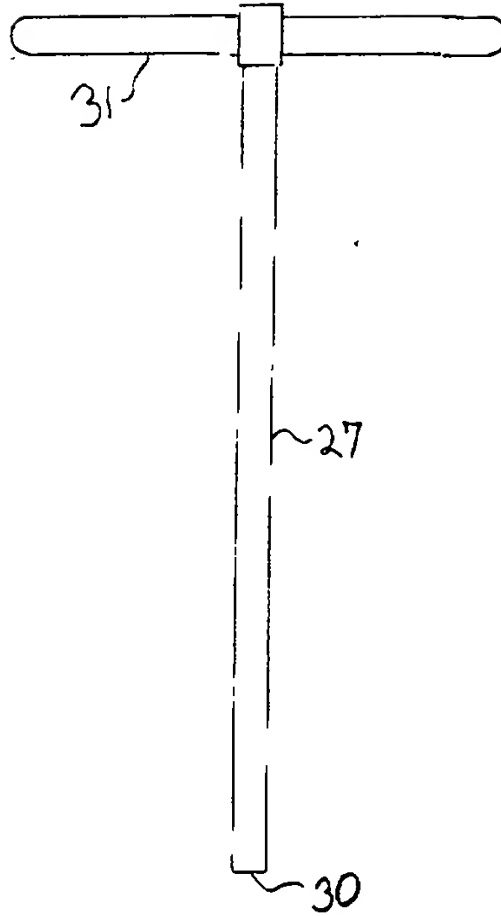
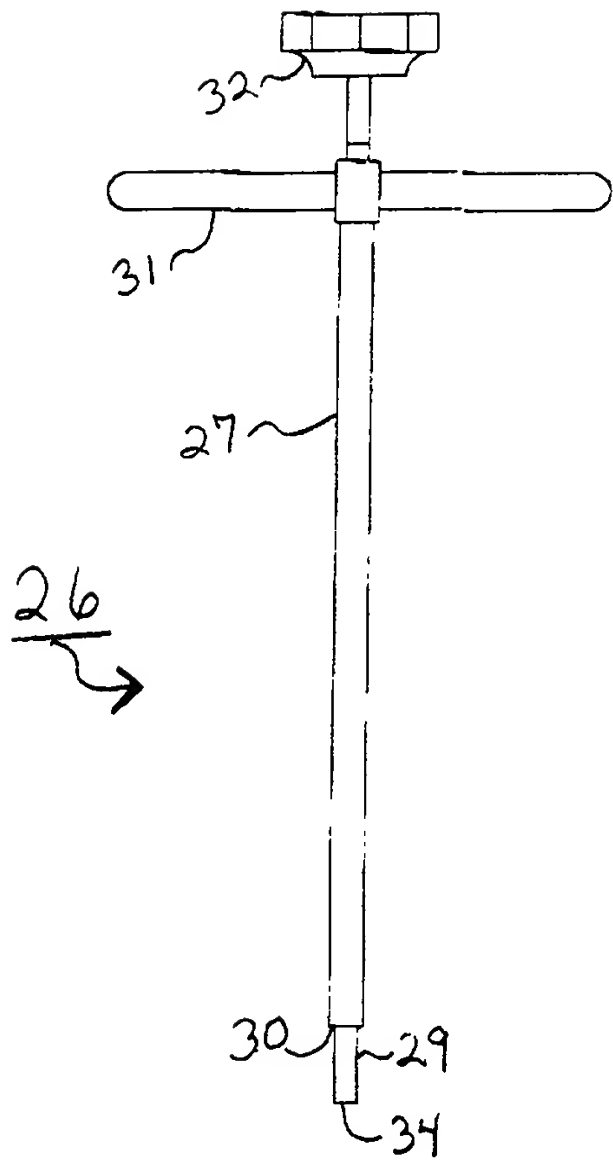


FIG. 2



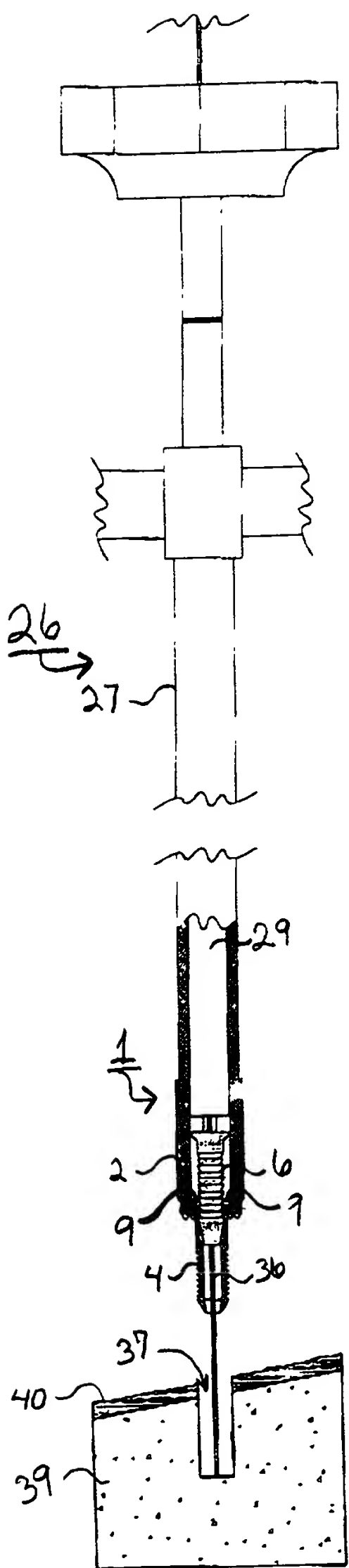


FIG. 6

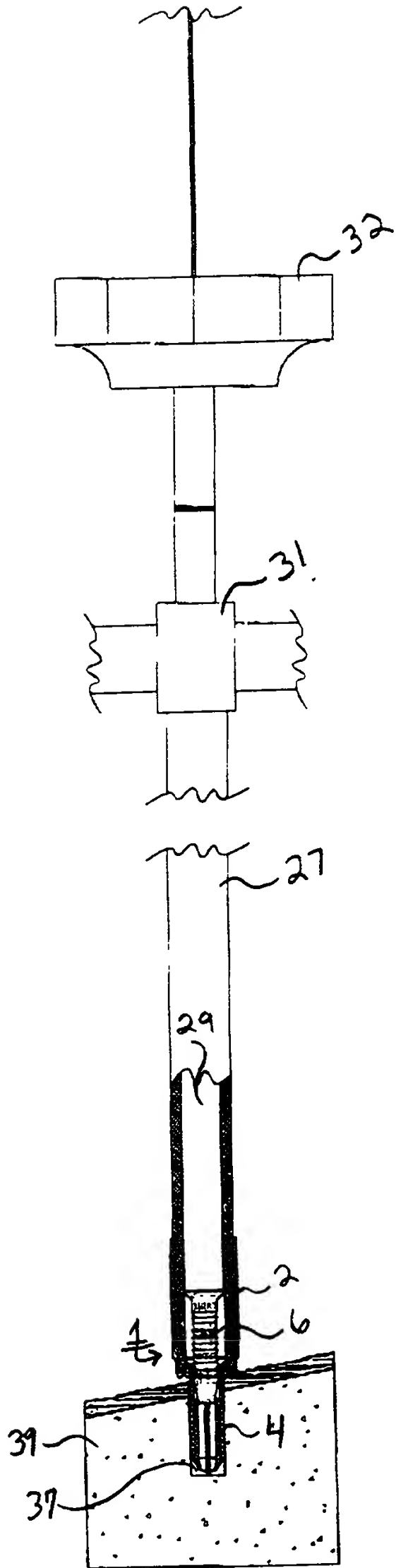


FIG. 7

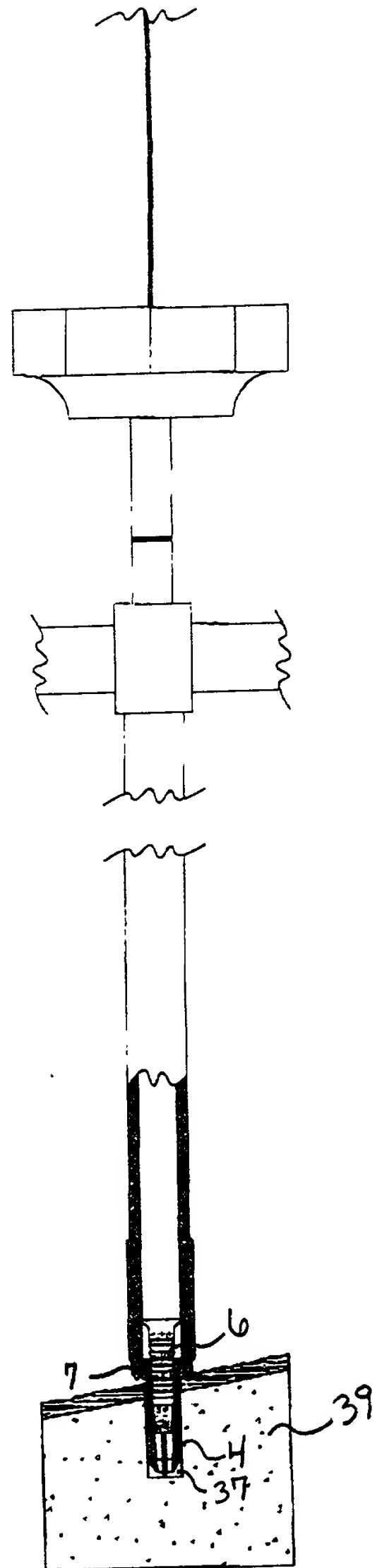


FIG. 8

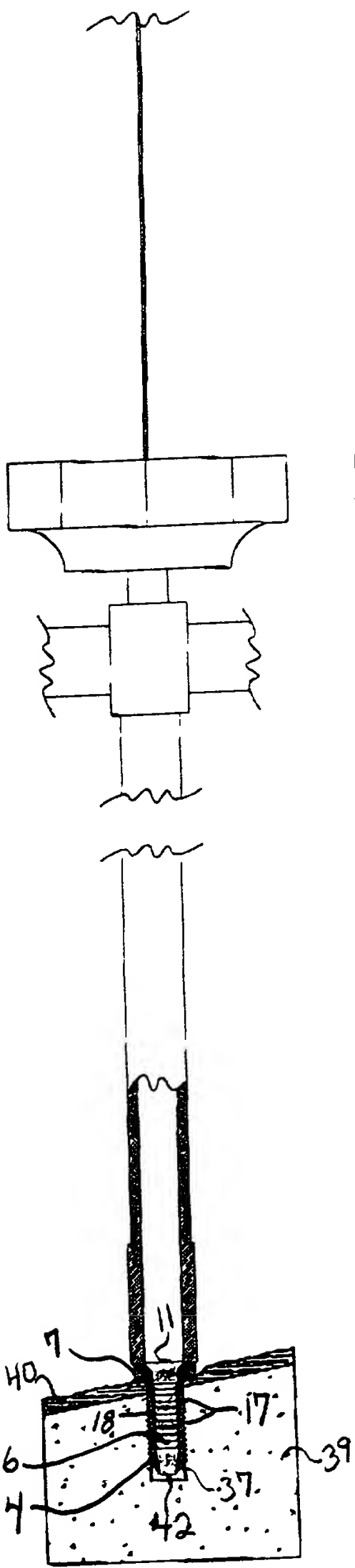


FIG. 9

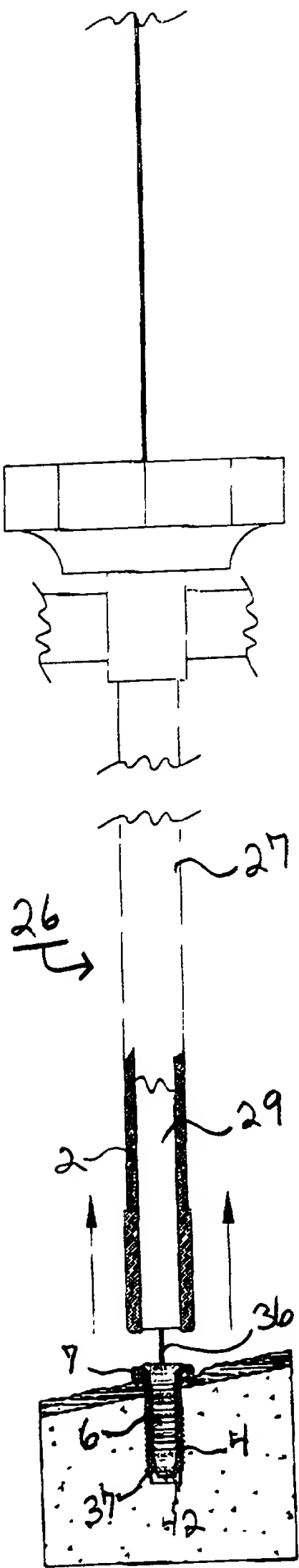


FIG. 10

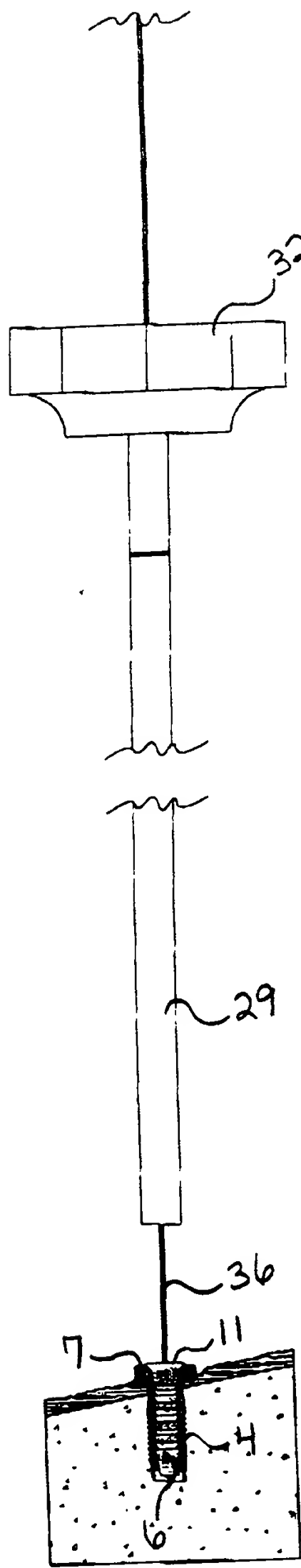


FIG. 11

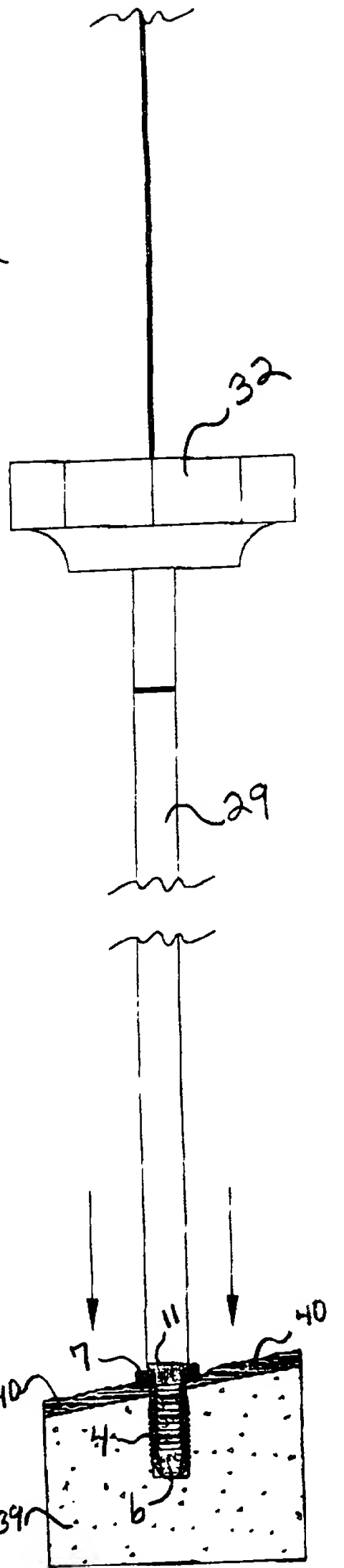


FIG. 12

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

BONE ANCHOR AND DEPLOYMENT DEVICE THEREFOR

the specification of which
(check one)

 X is attached hereto
 filed on _____
as Application Serial No. _____
 or Express Mail No. _____
and was amended on _____
(if applicable)

I do not know and do not believe that the subject matter of this application was ever known or used in the United States before my invention thereof or patented or described in any printed publication in any country before my invention thereof or more than one year prior to the date of this application, and that said subject matter has not been patented or made the subject of an issued inventor's certificate in any country foreign to the United States on an application filed by me or my legal representatives or assigns more than twelve months prior to the date of this application; that I acknowledge my duty to disclose information of which I am aware which is material to the examination of this application, that no application for patent or inventor's certificate on the subject matter of this application has been filed by me or my representatives or assigns in any country foreign to the United States, except those identified below, and that I have reviewed and understand the contents of the specification, including the claims as amended by any amendment referred to herein.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor’s certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor’s certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

Check one:

- ☐ no such applications have been filed.
- ☐ such applications have been filed as follows

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

| Country | Application Number | Date of Filing (month,day,year) | Priority Claimed Under 35 USC 119 |
|---------|--------------------|------------------------------------|--|
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

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| |

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application. As to subject matter of this application which is common to my earlier United States application, if any, described below, I do not believe that the same was ever known or used in the United States before my invention thereof or patented or described in any printed publication in any country before my invention thereof or more than one year prior to said earlier application, or in public use or on sale in the United States more than one year prior to said earlier application, that the said common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of said earlier application in any country foreign to the United States on an application, filed by me or my legal representatives or assigns more than twelve months prior to said application and that no application for patent or inventor's certificate on said subject matter has been filed by me or my representatives or assigns in any country foreign to the United States except those identified herein.

| | (Filed) | (patented,pending, abandoned) |
|-----------------------------|---------|----------------------------------|
| U.S. Application 08/595,772 | 2/2/96 | pending |
| U.S. Application 08/814,149 | 3/10/97 | pending |
| U.S. Application 08/163,130 | 12/6/93 | patented |
| U.S. Application 08/765,445 | 9/25/91 | patented |
| U.S. Application 08/588,025 | 9/25/90 | abandoned |

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

| | |
|----------------------|-----------------|
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| Sam Pasternack | Reg. No. 29,576 |
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Wherefore I petition that letters patent be granted to me for the invention or discovery described and claimed in the attached specification and claims, and hereby subscribe my name to said specification and claims and to the foregoing declaration, power of attorney, and this petition.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| | |
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